Section 1. 510 (k) Summary

a) Submitter:

Sunder Biomedical Tech. Co., Ltd
Contact person: Tony Hung
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Date Summary prepared: 11/15/2002

b) Device

Device trade name: Sunder Central Venous Catheter Kit
Device common name: Central Venous Catheter (CVC)
Device Classification name: Short-term catheters (less than 30 days) –Percutaneous Intravascular catheter

c) Legally marketed device to which the device is substantially equivalent

ARROW g^+ and blue Plus™ Multi-Lumen Central Venous Catheter 510(k) No.: K993691

d) Description of the device

The medical device made by Sunder Biomedical Tech, CO., LTD are triple-lumen, polyurethane catheter, 5.5 and 7.0 French in size, with three independent non-communication lumens, extension lines, luer hubs and slide clamps, placed within a vein and whose distal end is intended to be located within the vena cava (inferior of superior). Central Venous Catheter (CVC) - a tubular device with single lumen or multi-lumen catheter, or cannula, placed within a vein and whose distal end is intended to be located within the vena cava (inferior of superior).

The catheterization kit components are configured in a Polyester Terephthalate (PET) tray and sealed with a Tyvek lid stock, and sterilized.

e) Intended use of the device

The triple lumen central venous Catheter is intended for vascular access infusion and withdrawal of blood, blood products, and fluids, central venous blood pressure monitoring (CVP) plasma pheresis, acute hyperalimentation, continuous or int4ermittent drug infusion.

f) Performance tests:

The following performance tests are included in the submission:

1. Functional testing
   - **Tensile strength and elongation test**
   - **Anti-corrosive**
   - **Catheter-flexural fatigue tolerance test**

- Stiffness test
- Flow rate
- Catheter burst pressure test, Catheter collapse test
- Leakage test
- Ink adhesion test

2. Validation (Microbiological test)
   - Sterilization Process Validation
   - E.O. residual test
3. Biocompatibility (Biological tests)

The result of the laboratory tests demonstrate that the device is as safe as and is effective with the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2003

Mr. Tony Hung
President
Sunder Biomedical Tech. Co. Ltd.
10F-1, 1-67, Wu-Chung Road
Taichung City 403
TAIWAN R.O.C.

Re: K024007
Trade/Device Name: Sunder Central Venous Catheter Kits (SD-3L70F30J and SD-3L55F30J)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: May 26, 2003
Received: May 28, 2003

Dear Mr. Hung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 4.

510(k) Number (if known): K024007

Device Name: SUNDER CENTRAL VENOUS CATHETER KITS (SD-3L70F30J AND SD-3L55F30J)

Indications for Use:

The triple lumen central venous Catheter is intended for vascular access infusion and withdrawal of blood, blood products, and fluids, central venous blood pressure monitoring and continuous or intermittent drug infusion.

- Patients requiring multiple sites for IV access.
- Patients lacking useable peripheral IV sites.
- Patients requiring central venous pressure monitoring.
- Patients requiring total parenteral nutrition.
- Patients receiving incompatible medications.
- Patients requiring multiple infusions of fluids, medications, or chemotherapy.
- Patients subject to frequent blood sampling or receiving blood transfusions.
- Patients receiving infusions that are hypertonic, hyperosmolar or infusions that have divergent pH values.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Patricia Cucente

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K02 4007